FILED UNDER SEAL

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA

PLAINTIFFS UNDER SEAL	**Civil Action No. 1:10cv6 (J. Wilson)**
v.	**FILED UNDER SEAL**
DEFENDANTS UNDER SEAL	**JURY TRIAL DEMANDED**

SECOND AMENDED COMPLAINT FOR FALSE CLAIMS ACT VIOLATIONS 31 U.S.C. § 3729, ET SEQ.

W. Scott Simmer (admitted *pro hac vice*)
Thomas J. Poulin (admitted *pro hac vice*)
Blank Rome LLP
Watergate
600 New Hampshire Avenue, NW
Washington, DC 20037
Telephone: (202) 772-5967
Facsimile: (202) 572-8412

Nicholas C. Harbist (admitted *pro hac vice*)
Blank Rome LLP
One Logan Square
Philadelphia, PA 19103
Telephone: (215) 569-5500
Facsimile: (215) 569-5555

Wyatt B. Durrette, Jr. (VA Bar # 4719)
John B. Russell, Jr. (VA Bar # 17991)
Kenneth D. McArthur, Jr. (VA Bar #39467)
DurretteBradshaw, PLC
Bank of America Center, 16th Floor
1111 East Main Street
Richmond, VA 23219
Telephone: (804) 775-6900
Facsimile: (804) 775-6911

Counsel for Relator

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA

UNITED STATES OF AMERICA *ex rel.* THOMAS J. SPETTER, JR. and on behalf of the STATES of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WISCONSIN, and the DISTRICT OF COLUMBIA **Plaintiffs,** **v.** **ABBOTT LABORATORIES, INC., OMNICARE, INC., PHARMERICA CORPORATION and JOHN DOES #1-100, FICTITIOUS NAMES,** **Defendants.**	**Civil No. 1:10cv6 (J. Wilson)** **FILED UNDER SEAL** **JURY TRIAL DEMANDED**

TABLE OF CONTENTS

SECOND AMENDED COMPLAINT FOR FALSE CLAIMS ACT VIOLATIONS, 31 U.S.C. § 3729, *ET SEQ.* AND STATE LAW COUNTERPARTS

This is an action brought on behalf of the United States of America, the states below, and the District of Columbia (hereinafter "states" shall include District of Columbia) by Thomas J. Spetter, Jr. by and through his attorneys, against Defendants pursuant to the qui tam provisions of the Federal Civil False Claims Act, 31 U.S.C. § 3729, *et seq.*; the California False Claims Act, CAL. GOV'T CODE § 12650 (Deering 2000), *et seq.*; the Colorado Medicaid False Claims Act, COLO. REV. STAT. § 25.5-4-303.5 (2010), *et seq.*; the Connecticut False Claims Act, 2009 CONN. PUB. ACTS No. 09-5 (Sept. Spec. Sess.), *et seq.*; the Delaware False Claims and Reporting Act, DEL. CODE ANN. Tit. 6, § 1201 (2000), *et seq.*; the District of Columbia False Claims Act, D.C. CODE ANN. § 2-308.13 (2000), *et seq.;* the Florida False Claims Act, FLA. STAT. 68-081 (2000), *et seq.*; the Georgia False Medicaid Claims Act, GA. CODE ANN.§ 49-4-168 (2007), *et seq.*; the Hawaii False Claims Act, HAW. REV. STAT. § 661-22, (2006) *et seq.*; the Illinois Whistleblower Reward and Protection Act, 740 ILL. COMP. STAT. ANN. § 175/1 (2000), *et seq.*; the Indiana False Claims and Whistleblower Protection Act, INDIANA CODE § 5-11-5.5, (2007), *et seq.*, the Louisiana Medical Assistance Programs Integrity, LA. REV. STAT. ANN. § 46.439.1 (2006), *et seq.;* the Maryland False Health Claims Act of 2010, M.D. CODE ANN. ch. 4, § 2-601 (2010), *et seq.*; the Massachusetts False Claims Act, MASS. ANN. LAWS ch. 12, § 5(A), (2007) *et seq.*; the Michigan Medicaid False Claims Act, MICH. COMP. LAWS SERV. § 400.601, (2007) *et seq.* (2007); the Minnesota False Claims Act, MINN. STAT. § 15C.01 (2010), *et seq.*; the Montana False Claims Act, MONT. CODE ANN. § 17-8-401 (2005), *et seq.*; the Nevada Submission of False Claims to State or Local Government Act, NEV. REV. STAT. § 357.010 (1999), *et seq.*; the New Hampshire Medicaid False Claims Act, N.H. REV. STAT. ANN. § 167:61-b (2005), *et seq.*; the New Jersey False Claims Act, N.J. STAT. ANN. §

265 (2007); the New Mexico Medicaid False Claims Act, N.M. STAT. ANN. § 27-14-1 (2007), *et seq.*; the New York False Claims Act, N.Y. CLS ST. FIN. § 190.6. (2007), *et seq.*; the North Carolina False Claims Act, N.C. GEN. STAT. § 1-605 (2010), *et seq.*; the Oklahoma Medicaid False Claims Act, OKLA. STAT. tit. 63, § 5053 (2007), *et seq.*; the Rhode Island False Claims Act, R.I. GEN. LAWS § 9-1.1-1 (2008), *et seq.*; the Tennessee Medicaid False Claims Act, TENN. CODE ANN. § 71-5-181(c) (2006), *et seq.*; the Texas Human Resources Code, TEX. HUM. RES. CODE § 36.001 (2006), *et seq.*; the Virginia Fraud Against Taxpayers Act, VA. CODE ANN. § 8.01-216.1 (2006), *et seq.*, and the Wisconsin False Claims for Medical Assistance Act, WIS. STAT. § 20.931 (2007), *et seq.*; ("State *Qui Tam* statutes" or "*Qui Tam* States").

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States and the States arising from false and/or fraudulent records, statements, and claims made, used, and caused to be made, used, or presented by Defendants Abbott Laboratories ("Abbott"), Omnicare, Inc. ("Omnicare"), and PharMerica Corporation ("PharMerica") (collectively "Defendants"), and/or their agents, employees, or co-conspirators under the False Claims Act and the State *Qui Tam* statutes.

2. As alleged herein, Defendants engaged in a scheme since January 1, 1998 and continuing until January 1, 2009 to submit and/or cause to be submitted hundreds of thousands of false claims to federal and state health care programs by systematically and illegally promoting Depakote®, Depakote Sprinkles®, and Depakote ER® (the "Depakote® Products") for unapproved, off-label uses in long-term care facilities, assisted living facilities, mental retardation/developmentally disabled ("MRDD") facilities and other like facilities (collectively

"LTC facilities") throughout the United States. In addition, Defendant Abbott paid Defendants Omnicare and PharMerica substantial and illegal kickbacks to promote the fraudulent, off-label use of the Depakote® Products and/or to switch from competitor products to the Depakote® Products in LTC facilities serviced by Omnicare and PharMerica. These false claims cheated the federal and state Governments out of hundreds of millions of dollars that should not have been paid, thereby enriching the Defendants, and subjected patients to non-approved, ineffective, and unsafe uses of the Depakote® Products.

3. The off-label indications Defendant Abbott unlawfully promoted for the Depakote® Products include agitation and aggression associated with the treatment of patients with dementia, schizophrenia, bipolar disorder, post-traumatic stress disorder ("PTSD") (*e.g.,* in returning Iraqi war veterans), explosive temper/mood lability (especially in children), MRDD, impulsive-aggressive spectrum disorder (including ADHD, Tourette's, obsessive-compulsive disorder ("OCD"), developmental disorders (including autism), impulse control disorders, substance abuse disorders, sexual compulsions, and Cluster B personality disorders such as borderline personality disorder, and gambling disorder). The Defendants' unlawful, off-label promotion, and conspiracy to engage in the unlawful acts described in this Second Amended Complaint caused, or it was foreseeable that they would cause, false and fraudulent claims for payments to be made to Federal and State programs.

4. Defendant Abbott, *inter alia,* (a) knowingly disregarded federal law and formal guidance issued by the Food and Drug Administration ("FDA") regarding off-label promotion; (b) knowingly misrepresented the evidence concerning the efficacy and safety of the off-label uses of the Depakote® Products; (c) knowingly promoted the Depakote® Products for uses that were neither effective nor safe; (d) knowingly created off-label consensus guidelines concerning

the Depakote® Products' off-label uses that appeared to have been written by independent researchers, but, in fact, were sponsored and/or ghost-written by Defendant Abbott and/or its agents; (e) improperly disseminated such publications to physicians as a result of improper solicited requests by sales representatives; (f) paid financial inducements to "key opinion leaders" ("KOLs") who gave presentations concerning the off-label uses of the Depakote® Products, either at promotional speaker programs or at continuing medical education ("CME") events; (g) funded so-called "independent" consensus guidelines that touted the illegal and off-label use of the Depakote® Products for the treatment of agitation and aggression associated with dementia, purportedly prepared by unbiased "experts," when, in truth, these "experts" were paid by Abbott, all for the purpose of increasing sales of the Depakote® Products; and (h) funded the creation and dissemination of "standing orders" so that patients would be treated with the Depakote® Products off-label and without a physician's having to write a prescription.

5. In furtherance of this fraudulent scheme, and integral to its massive scope and impact, Defendant Abbott paid Defendants Omnicare and PharMerica millions of dollars in kickbacks in the form of illegal rebates and other inducements to ensure they would, *inter alia* (a) illegally promote the off-label uses of the Depakote® Products through "in-services," "lunch 'n learns," "round tables," and speaker programs (discussed in detail below) in LTC facilities and to physicians throughout the United States; (b) conduct opportunistic routine "chart reviews" of LTC patients' medical records to identify opportunities to "convert" other prescribed drugs to the Depakote® Products; (c) obtain prior physician authorization letters ("PALs") or Global Authorization Forms ("GAFs") from physicians to convert from competing (frequently less-expensive) drugs to the off-label and illegal use of the Depakote® Products; and (d) insert

deliberately misleading "standing orders" into patient files, calling for the off-label use of the Depakote® Products to treat agitation and aggression associated with dementia.

II. JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over this action pursuant to 31 U.S.C. § 3732(a), 28 U.S.C. § 1331, and 28 U.S.C. § 1345. The Court has original jurisdiction of the State law claims pursuant to 31 U.S.C. § 3732(b) because this action is brought under State laws for the recovery of funds paid by the *Qui Tam* States, and arises from the same transaction or occurrence brought on behalf of the United States under 31 U.S.C. § 3730.

7. This Court has personal jurisdiction over the Defendants because, among other things, Defendants transact business in this District, and engaged in wrongdoing in this District. Specifically, Abbott has sales offices located in the Commonwealth of Virginia out of which it employs numerous sales representatives who call and visit healthcare care professionals throughout Virginia in order to sell the Depakote® Products. In addition, Defendant Abbott retained Insight Therapeutics, LLC—a Norfolk, Virginia company as an instrumentality in much of the fraudulent activity alleged herein. Defendant Omnicare operates pharmacies in Virginia, provides services to long-term care facilities in Virginia, and conducted training meetings for the off-label uses of the Depakote® Products in Virginia. Defendant PharMerica engaged in illegal activity in the Commonwealth of Virginia, and also operates institutional pharmacies in Virginia, including a pharmacy located at 9386 Hardy Road, Vinton, VA 24179-5690.

8. Venue is proper in this District under 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and (c). Defendants transact business within this District, and acts proscribed by 31 U.S.C. § 3729 occurred in this District. The Court has original jurisdiction of the State law claims pursuant to 31 U.S.C. § 3732(b) because this action is brought under State laws for the

recovery of funds paid by the *Qui Tam* States, and arises from the same transaction or occurrence as the claims brought on behalf of the United States under 31 U.S.C. § 3730.

9. The causes of action alleged herein are timely brought because of, among other things, Defendants' efforts to conceal from the United States their wrongdoing in connection with the allegations made herein.

III. PARTIES

A. PLAINTIFF/RELATOR THOMAS J. SPETTER, JR.

10. Plaintiff/Relator Thomas J. Spetter, Jr. ("Relator Spetter") is a resident of San Diego, California. Relator Spetter was employed by Abbott Laboratories ("Abbott") for over twelve years, from June 1994 through October 2006. Relator Spetter holds a Bachelors of Science in psychology and a Masters in Business Administration. Relator Spetter began his career at Abbott in 1994 as a Medical Nutritional Representative in Abbott's Ross Products division in Seattle, Washington. In January 1998, Relator Spetter became a Neuroscience Long-Term Care Account Specialist in Abbott's Pharmaceutical Products Division. In 2000, he was promoted to a Senior Long-Term Care Neuroscience Account Specialist/Regional Field Trainer in San Diego, California. From July 2004 through November 2004, he worked as an Interim Neuroscience Regional Training Specialist for the Central Region in Abbott's Pharmaceutical Products Division at its Bannockburn, Illinois Regional Office. In 2004, he was promoted to Neuroscience Specialty Account Executive/SAE Regional Field Trainer, responsible for selling Depakote®, Depakote Sprinkles®, and Depakote ER® (hereinafter "the Depakote® Products"). In 2005, he was promoted to SAE-Territory Manager. Relator Spetter held this position until late 2006 when he left the company.

11. Relator Spetter earned multiple awards as a LTC Sales Representative, receiving the 1999 National All Star Award; the 1999 Depakote Achievers Award - National Spiff Contest Winner; and the 2002 Top 5 Percent National All Star Award. In 2004 he was the T2 West Coast LTC Marketing Spiff Contest Winner. In 2005, he was selected as the SAE Regional Field Trainer and Initial Sales Training Guest Trainer. In 2006, he was selected from the Top Abbott Account Executives for the 2006 Abbott Leadership Development Summit. He was responsible for over $3.3 million annually in sales of the Depakote® Products to long-term care facilities, hospitals, correctional facilities, MRDD facilities, and Department of Defense accounts.

12. Relator Spetter is an original source of the Fraudulent Marketing Scheme allegations in this Second Amended Complaint, and the allegations in the Fraudulent Marketing Scheme are not based upon publicly-disclosed information. In accordance with 31 U.S.C. § 3730(b)(2), Relator Spetter has provided the government with material information supporting his allegations prior to the filing of this Second Amended Complaint, including documents and videotapes.

B. DEFENDANT ABBOTT LABORATORIES

13. Defendant Abbott Laboratories ("Abbott") is an Illinois corporation with its principal place of business in Abbott Park, Illinois. Abbott's principal businesses are global pharmaceuticals, nutritionals, and medical products. The Abbott Pharmaceutical Products Division ("PPD") is the pharmaceutical division of Abbott. In 2008, Abbott had over $29 billion in revenue.

14. Abbott's PPD divides its business into franchises. For example, some of PPD's divisions include the Neuroscience franchise, the Anti-Infective/Gastrointestinal franchise, the HIV/AIDS franchise, and the Cardiovascular franchise. Within each franchise, each segment of

business has its own separate sales forces. Within the Neuroscience franchise, up until 2004 there were the Bipolar/Migraine/Epilepsy Sales Force, the Long-Term Care Sales Force (hereinafter the "LTC Sales Force"), and the Hospital Institution Sales Force. In 2004, the LTC Sales Force was merged into the Hospital Institution Sales Force to form the SAE Institutional Sales Force. The SAE Institutional Sales Force was disbanded effective January 1, 2009, and Abbott thereafter no longer had a sales force which sold its products in the LTC facility market.

15. Abbott manufactures, markets, and sells brand-name prescription drug products, including the Depakote® Products, which are paid for (or reimbursed by) various Governmental programs. These programs include health benefit carriers offering benefits under the Federal Employees Health Benefits ("FEHB") program under a prime contract with the Blue Cross Blue Shield Association ("BCBSA"), the Health Insurance Program for the Elderly and Disabled—more commonly referred to as "the Medicare Program," 42 U.S.C. § 1395, *et seq.* via Medicare Part C, also known as Medicare+Choice, Medicare Part D, the Indian Health Service, Medicaid, the Mail Handler's Health Benefit Plan ("MHHBP"), the U.S. Secret Service Employees Health Association ("SSEH") Health Benefit Plan, the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS," now known as "TRICARE"), and the Veteran's Health Administration ("VHA") (collectively, the "Federal Programs").

16. Abbott was a joint-venturer with Japan's Takeda Chemical Industries, Ltd. in TAP Pharmaceuticals. TAP Pharmaceuticals paid $875 million in a 2001 settlement of allegations that TAP had provided free and unreported samples of Lupron®, a prostate cancer drug, to physicians with the understanding that they would bill Medicaid and Medicare for reimbursements based on the inflated average wholesale price.

17. In July 2003, Abbott also agreed to pay $622 million in criminal and civil penalties to resolve allegations that its Ross Products Unit had defrauded Medicare and Medicaid by failing to report Best Prices. In that proceeding, the U.S. Attorney's Office in the Southern District of Illinois probed whether the Ross Products Unit had miscalculated Best Prices by discounting or giving away products to boost sales, which were then submitted to the Government for the purposes of obtaining reimbursements at higher prices.

18. As alleged more fully herein, Defendant Abbott conspired with Defendants Omnicare, Inc; PharMerica Corporation; and others to commit the unlawful acts described in this Second Amended Complaint. As a result of Abbott's actions, the *Qui Tam* States and the Federal Programs have suffered financial harm.

C. DEFENDANT OMNICARE, INC.

19. Defendant Omnicare, Inc. ("Omnicare") is a Delaware corporation with headquarters in Covington, Kentucky. Omnicare is the nation's largest provider of pharmacy services to LTC facilities. It provides services to approximately 1.4 million LTC residents in 47 states, including in the Commonwealth of Virginia. Omnicare's principal business is to fill prescriptions and to deliver drugs to patients in LTC facilities. As part of that business, Omnicare employed pharmacists who made recommendations to nursing home physicians about the drugs they should prescribe for their patients. In many cases, these recommendations were a product of business deals that Omnicare had struck with particular drug manufacturers. Thus, when Omnicare entered into a remunerative contract with one drug manufacturer, like Defendant Abbott for the Depakote® Products, Omnicare then directed its pharmacists to recommend that physicians prescribe more of that manufacturer's drugs, either by writing new prescriptions or by

agreeing that Omnicare could switch their patients' existing prescriptions to the drugs of the manufacturer with which Omnicare has a contract.

20. Omnicare started to operate in healthcare services in 1981. The company grew substantially through acquisition of other pharmaceutical businesses and service providers. Many major acquisitions came in the latter part of the 1990's and have since continued through 2008. It has, in total, acquired approximately 50 companies with its latest acquisition coming in July 2008.

21. Omnicare has, in the past, been subject to multi-million dollar settlements for Medicaid fraud and illegal kickbacks. In December 2008, the United States announced that Omnicare had agreed to pay $102 million to settle Medicaid fraud cases in 43 states. One complaint accused Omnicare of switching two drugs from tablet to capsule form to boost Medicaid payments. As part of the settlement, Omnicare agreed to enter into a five-year corporate integrity agreement.

22. On November 3, 2009, the United States announced it was settling claims against Omnicare for $98 million, related to activity strikingly similar to the activity herein alleged against Omnicare. Specifically, it was alleged that Omnicare had solicited and received kickbacks from Johnson & Johnson (hereinafter "J&J") in exchange for agreeing to recommend that physicians prescribe Risperdal®, a J&J antipsychotic drug, to nursing home patients. J&J's kickbacks to Omnicare took multiple forms, including rebates that were conditioned on Omnicare engaging in an "Active Intervention Program" for Risperdal® and payments disguised as data purchase fees, educational grants, and fees to attend Omnicare meetings.

23. During the relevant time period, from at least 1998 through the present, after Omnicare delivered drugs to patients in LTC facilities, it caused reimbursement claims to be

submitted on behalf of those patients to their insurers, including Medicaid and Medicare. Omnicare is a party to provider agreements with each of the state Medicaid programs to which it submits drug reimbursement claims.

24. As alleged more fully herein, Defendant Omnicare conspired with Defendant Abbott and others to commit the unlawful acts described in this Second Amended Complaint. As a result of Omnicare's actions, the *Qui Tam* States and Federal Programs have suffered financial harm.

D. DEFENDANT PHARMERICA CORPORATION

25. PharMerica Corporation (hereinafter "PharMerica") is a corporation organized under the laws of the State of Delaware with a principal place of business in Louisville, Kentucky. PharMerica is the second largest institutional pharmacy services company in the United States, based on revenues, and operates 97 institutional pharmacies in 41 states, including institutional pharmacies in the Commonwealth of Virginia. PharMerica's customers are typically LTC facilities. PharMerica is generally the primary source for supplying pharmaceuticals to its LTC facility customers. PharMerica's core business provides pharmacy products and services to residents and patients in LTC facilities. It purchases, repackages, and dispenses prescription and non-prescription pharmaceuticals in accordance with physician orders and delivers medications to healthcare facilities for administration to individual patients and residents.

26. After being acquired by AmerisourceBergen Corporation in 1998, PharMerica again became a stand-alone company on October 23, 2006, when Kindred Healthcare, Inc. and AmerisourceBergen spun-off and combined their respective institutional pharmacy businesses, Kindred Pharmacy Services and PharMerica Long-Term Care. PharMerica is the successor in interest to the liabilities of Kindred Pharmacy Services and PharMerica Long-Term Care.

27. As part of its business, PharMerica employs consultant pharmacists who make recommendations to nursing home physicians about the drugs they should prescribe for their patients. In many cases, these recommendations are a product of business deals that PharMerica consummated with particular drug manufacturers, including with Defendant Abbott. Thus, when PharMerica entered into a remunerative contract with a drug manufacturer, such as with Defendant Abbott for the Depakote® Products, PharMerica then directed its consultant pharmacists to recommend that physicians prescribe more of that manufacturer's drugs, either by writing new prescriptions or by agreeing that PharMerica could switch their patients' existing prescriptions to the drugs of the manufacturer with which PharMerica has a contract.

28. PharMerica has, in the past, been subject to multi-million dollar settlements for receiving illegal kickbacks. On March 3, 2005, PharMerica Drug Systems, Inc. and PharMerica, Inc. (collectively "PharMerica"), agreed to pay $5,975,000 and to enter into a corporate integrity agreement to resolve its liability for kickback payments. The OIG alleged that PharMerica had entered into a purchase and sale agreement with the owners of a nursing facility chain to acquire the chain's institutional pharmacy for $7.2 million. PharMerica allegedly conditioned its purchase of the pharmacy on the creation of a pharmacy services agreement (PSA) that contractually required the nursing facilities to order its drugs from the pharmacy. On June 11, 2009, the United States announced it had entered into a settlement agreement with Kindred Healthcare, Inc. and its successor PharMerica Pharmacy, LLC, to pay some $1.3 million to settle claims that Kindred violated state and federal laws regarding billing TennCare and the Medicaid program for pharmaceuticals that were not actually delivered.

29. During the relevant time period, from at least 1998 through the present, after PharMerica delivered drugs to patients in LTC facilities, it caused reimbursement claims to be

submitted on behalf of those patients to their insurers, including Medicaid. PharMerica (and/or its predecessors in interest) was a party to provider agreements with each of the state Medicaid programs to which it submits drug reimbursement claims.

30. As alleged more fully herein, Defendant PharMerica conspired with Defendants Abbott and others to commit the unlawful acts described in this Second Amended Complaint. As a result of PharMerica's actions, the *Qui Tam* States and Federal Programs have suffered financial harm.

31. Defendants Omnicare and PharMerica are collectively referred to herein as the "Institutional Pharmacy Defendants."

E. DEFENDANTS JOHN DOES #1-100

32. John Does #1-100, fictitious names, are individuals, corporations, limited liability companies, or other lawful business entities through which Defendants do business in the United States and internationally, and who are unknown co-conspirators who conspired with Abbott to perpetuate the scheme as described herein. To the extent that any of the conduct or activities described in this Second Amended Complaint were not performed by Defendants, but by the individuals or entities described herein as John Does #1-100, fictitious names, any reference herein to Defendants under such circumstances, and only under such circumstances, refers also to John Does #1-100 and/or other co-conspirators who conspired with Defendants to perpetrate the schemes described herein.

33. As a result of actions of John Does #1-100, the *Qui Tam* States and Federal Programs have suffered financial harm.

IV. SUMMARY OF DEFENDANTS' ILLEGAL CONDUCT

A. THE PLAN AND PURPOSE OF THE FRAUDULENT MARKETING SCHEME

34. It was the plan and purpose of Defendant Abbott's scheme to illegally promote the Depakote® Products' off-label use, beginning at least as early on January 1, 1998 and continuing to January 1, 2009, in order to fraudulently obtain Government reimbursement by causing false and fraudulent claims to be submitted for payment and causing false and fraudulent statements to be made so as to maximize Abbott's profits.

35. It was the plan and purpose of the Institutional Pharmacy Defendants' scheme to fraudulently obtain Government reimbursement by conspiring with Abbott, and thereby causing false and fraudulent claims for off-label uses to be submitted for payment in order to maximize Defendant Abbott's profits, in exchange for receiving kickbacks. This scheme began as early as 1998 and is currently ongoing.

B. THE MANNER AND MEANS OF EXECUTING DEFENDANT ABBOTT'S FRAUDULENT MARKETING SCHEME

36. As part of the scheme, Defendant Abbott illegally promoted the off-label sales and use of the Depakote® Products in order to obtain reimbursement for non-medically accepted indications and other off-label uses, thereby maximizing profits by making false and fraudulent statements to the public, healthcare professionals and the Food and Drug Administration ("FDA").

37. It was further part of the scheme that Abbott attempted to conceal and cover up the off-label promotion of the Depakote® Products by making false statements to the FDA and directing employees to conceal evidence.

38. The scheme had a material effect on the Government's decision to pay for the Depakote® Products. Had the Government known that reimbursements were being made for Depakote® Products that were being used off-label as a result of Defendants' unlawful promotion, the Government would not have made such reimbursements.

39. The scheme, described below, is referred to herein as the "Defendant Abbott's Fraudulent Marketing Scheme."

C. THE MANNER AND MEANS OF EXECUTING THE INSTITUTIONAL PHARMACY DEFENDANTS' FRAUDULENT SCHEME

40. It was part of the scheme that the Institutional Pharmacy Defendants received kickbacks from Defendant Abbott. In exchange, the Institutional Pharmacy Defendants agreed to promote the off-label sales and uses of the Depakote® Products, and to undertake chart reviews as well as other activities to increase the use of the Depakote® Products.

41. The Institutional Pharmacy Defendants made false and fraudulent statements to the public and healthcare professionals when they promoted the off-label use of the Depakote® Products and in converting elderly LTC patients' prescriptions to the Depakote® Products.

42. The Institutional Pharmacy Defendants also ensured that claims for the Depakote® Products were submitted to the Government through the unlawful making of a false record or statements for the purpose of inducing the Government to pay the false or fraudulent claim.

43. In submitting reimbursements for the off-label use of the Depakote® Products, the Institutional Pharmacy Defendants thereby defrauded the Federal and State government programs by procuring reimbursements that they would not have been entitled to had these programs known about the Institutional Pharmacy Defendants' involvement in Abbott's off-label marketing plan.

44. The scheme, described below, is referred to herein as the "Institutional Pharmacy Defendants' Fraudulent Scheme."

V. FDA REGULATION OF DRUG MARKETING AND PROMOTION

A. THE FDA REGULATES WHAT DRUGS MAY BE MARKETED, AND THE USES FOR WHICH THEY MAY BE MARKETED

45. Under the Food, Drug and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301-97, new pharmaceutical drugs cannot be marketed or sold in the United States unless the sponsor of the drug demonstrates to the satisfaction of the FDA that the drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a), (d). Approval of the drug by the FDA is the final step in a multi-year process of study and testing.

46. To determine whether a drug is "safe and effective," the FDA relies on information provided by a drug's manufacturer; it does not, itself, conduct any substantial analyses or studies. Applications for FDA approval (known as New Drug Applications or "NDAs") must include "full reports of investigations which have been made to show whether or not such drug is safe for use and whether or not such drug is effective in use." 21 U.S.C. § 355(b)(1)(A).

47. Under U.S. food and drug laws, a drug may not be introduced into interstate commerce unless its sponsor has shown that the drug is safe and effective for the intended conditions of use. *See* 21 U.S.C. § 321. The law requires that "adequate and well-controlled investigations" be used to demonstrate a drug's safety and effectiveness. *See* 21 U.S.C. § 355(d)(7). The FDA approves a drug if there are "adequate and well-controlled clinical trials" that demonstrate a drug's safety and effectiveness for its "intended conditions" of use. *See* 21 U.S.C. § 355(d)(5). The "intended conditions" for use of a drug are listed in the drug's labeling, which is reviewed and approved by the FDA. *See* 21 U.S.C. § 355(d)(1) & (2). Indications for use that are not listed in a drug's labeling have not been approved by the FDA. *See* 37 Fed. Reg. 16,503 (1972).

48. The standards that govern the FDA safety and effectiveness requirements are contained in statutes, regulations, notices, and guidance documents. The statutory requirement that a drug's effectiveness be demonstrated by "adequate and well-controlled clinical investigations" has been interpreted to mean a clinical study with (1) clear objectives; (2) adequate design to permit a valid comparison with a control group; (3) adequate selection of study subjects; (4) adequate measures to minimize bias; and (5) well defined and reliable methods of assessing subjects' responses to treatment. *See* 21 C.F.R. § 314.26.

49. The FDA has set forth general principles for the conduct and performance of clinical trials. These principles have been adopted not only by the agency, but also by the International Conference on Harmonisation, which includes the world's leading medicine control agencies. *See* International Conference on Harmonisation: Guidance on General Considerations for Clinical Trials, 62 Fed. Reg. 66113 (Dec. 17, 1997).

50. Those principles include the following standards for the conduct of clinical trials to support an agency decision that a drug is safe and effective for its intended conditions for use:

- The need for trials to be controlled: "Trials should have an adequate control group. Comparisons may be made with placebo, no treatment, active controls, or of different doses of the drug under investigation. The choice of the comparator depends on, among other things, the objective of the trial. . . . Historical (external) controls can be justified in some cases, but particular care is important to minimize the likelihood of erroneous inference."
- The need for trials to be randomized: "In conducting a controlled trial, randomized allocation is the preferred means of assuring comparability of test groups and minimizing the possibility of selection bias."

- The need for trials to be blinded: "Blinding is an important means of reducing or minimizing the risk of biased study outcomes. A trial where the treatment assignment is not known by the study participant because of the use of placebo or other methods of masking the intervention is referred to as a single blind study. When the investigator and sponsor staff who are involved in the treatment or clinical evaluation of the subjects and analysis of data are also unaware of the treatment assignments, the study is double blind."
- The need for objective and prospectively determined trial endpoints: A drug's effectiveness is determined if the drug has an effect on an "endpoint." That endpoint can be a clinical benefit, such as survival or a reduction of pain as measured on a validated pain scale; a clinical measurement, such as blood pressure; and, in some cases, a laboratory measurement, such as the amount of virus in the blood stream. All endpoints need to reflect clinical benefit. An endpoint that indirectly reflects a clinical benefit, such as a laboratory measurement, is known as a "surrogate endpoint." Endpoints should be defined prospectively (*i.e.*, before the trial begins), giving descriptions of methods of observation and quantification. Objective methods of observation should be used where possible and when appropriate. A primary endpoint should reflect clinically relevant effects and is typically selected based on the principal objective of the study. Secondary endpoints assess other drug effects that may or may not be related to the primary endpoint. Endpoints and the plan for their analysis should be prospectively specified in the protocol. The method used to make the measurements of the endpoints, both subjective and objective, should be

validated and meet appropriate standards for accuracy, precision, reproducibility, reliability and responsiveness (sensitivity to change over time).

51. The FDA has addressed the need for reproducibility and reliability of clinical data in the trials that support a drug's approval. The FDA generally requires two pivotal, adequate and well-controlled trials to support approval, except in certain circumstances. As stated by the FDA in its 1998 *Guidance to the Industry*, "it has been FDA's position that Congress generally intended to require at least two adequate and well controlled studies, each convincing on its own, to establish effectiveness." *See* U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), *Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drugs and Biological Products*, May 1998. *See, e.g.,* Final Decision on Benylin, 44 FR 51512, 518 (Aug. 31, 1979). FDA's position is based on the language in the statute and the legislative history of the 1962 amendments. Language in a Senate Report suggested that the phrase "adequate and well-controlled investigations" was designed not only to describe the quality of the required data but also the "quantum" of required evidence. *See* S. Rep. No. 1744, Part 2, 87th Cong. 2d Sess. 6 (1962). Nevertheless, FDA has been flexible within the limits imposed by the Congressional scheme, broadly interpreting the statutory requirements to the extent possible where the data on a particular drug was convincing. In some cases, FDA has relied on pertinent information from other adequate and well-controlled studies of a drug (such as studies of other doses and regimens, of other dosage forms, in other stages of disease, in other populations, and of different endpoints) to support a single adequate and well-controlled study demonstrating effectiveness of a new use. In these cases, although there is only one study

of the exact new use, there are, in fact, multiple studies supporting the new use, and expert judgment could conclude that the studies together represent substantial evidence of effectiveness.

52. In a few cases, FDA has relied on only a single, adequate and well-controlled efficacy study to support approval – generally only in cases in which a single multicenter study of excellent design provided highly reliable and statistically strong evidence of an important clinical benefit, such as an effect on survival, and a confirmatory study would have been difficult to conduct on ethical grounds. In section 115(a) of the Modernization Act, Congress amended section 505(d) of the Act to make it clear that the Agency may consider "data from one adequate and well-controlled clinical investigation and confirmatory evidence" to constitute substantial evidence if FDA determines that such data and evidence are sufficient to establish effectiveness. In making this clarification, Congress confirmed FDA's interpretation of the statutory requirements for approval and acknowledged the Agency's position that there has been substantial progress in the science of drug development resulting in higher quality clinical trial data.

53. Cases where the FDA has approved a drug on the basis of one clinical trial plus confirmatory evidence are rare. They include instances of large, independently conducted multicenter trials with strong empirical results, with internal consistency across multiple outcomes, such that "sponsors faced ethical boundaries" in conducting a second placebo-based trial. Clinical trials that are not controlled, blinded, randomized and whose endpoints are not prospectively and objectively determined and measured may be used in early stage drug development phases, but are exceptionally unlikely to qualify as "adequate and well-controlled" clinical trials needed to support FDA approval.

54. After a drug is approved, the FDA continues to exercise control over the product labeling. To protect patients from safety concerns, the FDA may require a label change to reflect the increased risk of various side effects or interactions, restrict a drug's indications, or, in extreme cases, force a withdrawal from the market. *See* 21 C.F.R. § 201.57(3).

B. FDA REGULATIONS PROHIBIT OFF-LABEL MARKETING AND FALSE AND MISLEADING STATEMENTS ABOUT A DRUG'S USE.

55. FDA regulations restrict how drug companies may market and promote approved drugs. *See* 21 U.S.C. §§ 331, 352; 21 C.F.R. § 314.81. Drug labels – including all marketing and promotional materials relating to the drug – may not describe intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331, 352. Illegal "misbranding" can result in criminal penalties. *See* 21 U.S.C. § 333.

56. The same general requirements about the promotion of prescription drugs apply to both professional and consumer-oriented marketing. In particular, promotional materials may only make claims that are supported by "substantial" scientific evidence (according to strict scientific procedures) and they may not be false or misleading. FDA oversight helps ensure a "fair balance" in all promotional claims and materials. Federal regulations require that the risks as well as the benefits be clearly identified and given appropriate prominence. Promotional materials must be consistent with the FDA-approved product labeling. This restriction pertains to the clinical indications for which the drug has been approved as well as the dosing regimen that is supported by the clinical trials that were undertaken to establish safety and efficacy.

57. A manufacturer, like Abbott, wishing to market or otherwise promote an approved drug for uses other than those listed on the approved label, must resubmit the drug for a series of clinical trials similar to those required for the initial FDA approval. *See* Food and Drug Administration Modernization Act of 1997 ("FDMA"), 21 U.S.C. §§ 360aaa(b), (c); *see also* 21

C.F.R. § 314.54 (outlining the administrative procedure for filing an application for a new indication); 21 U.S.C. §§ 301 *et seq.* A supplemental NDA must be filed. Unless and until an additional indication is approved by the FDA, the unapproved use is considered to be "off-label."

58. "Off-label" refers to the use of an approved drug for any purpose, or in any manner, other than what is described in the drug's labeling. Off-label use includes treating a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified on the label, or treating a different patient population (*e.g.*, treating a child when the drug is approved to treat adults).

59. Although the FDA is responsible for ensuring that a drug is safe and effective for the specific approved indication, the FDA does not regulate the practice of medicine. Once a drug is approved for a particular use, the FDA does not prohibit physicians from prescribing the drug for uses that are different than those approved by the FDA. When considering off-label prescribing, physicians depend on the patient-specific evidence they have available to them. This includes the particular patient, the severity of his or her problems, the successfulness of prior treatment, and the risks of not treating. Whether contemplating on- or off-label use, physicians also rely on personal experience, recommendations from colleagues and academics, educational seminars, and clinical trials evidence. Much of what physicians rely on is information (or, as the case may be, *misinformation*) provided by sales representatives from drug makers, drug company sponsored CME courses and speaker programs, and drug company-sponsored clinical trials.

60. Although physicians may prescribe drugs for off-label usage, the law prohibits drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved, or for a patient group that is unapproved. Specifically, a manufacturer illegally

"misbrands" a drug if the drug's labeling (which includes all marketing and promotional materials relating to the drug) describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331, 352. Off-label information may be disseminated only in response to an "unsolicited request from a healthcare practitioner." 21 U.S.C. § 360aaa-6. In any other circumstances, a manufacturer is permitted to disseminate information concerning the off-label uses of a drug only after the manufacturer has submitted (a) an application to the FDA seeking approval of the drug for the off-label use, (b) the materials to the FDA prior to dissemination, and (c) the materials themselves are submitted unabridged in a form that is neither false nor misleading. 21 U.S.C. §§ 360aaa(b) & (c); 360aaa-1.§ 331(d), and its implementing regulations, and 21 C.F.R. § 202.1(e)(4)(i)(a) prohibit any advertising that recommends or suggests an off-label use for an approved drug, and the FDA has interpreted "advertising" to include a significant amount of speech that would not typically be considered advertising. *See Final Guidance on Industry-Supported Scientific and Educational Activities,* 62 Fed. Reg. 64,074 (Dec. 3, 1997). The FDA "interprets the term 'advertisement' to include information (other than labeling) that originates from the same source as the product and that is intended to supplement or explain the product."

61. Any manufacturer speech explaining one of its products is an "advertisement" for the product and is subject to the prohibitions against off-label marketing in 21 C.F.R. § 202.1, as well as the FDA's "fair balance" requirement, described *infra*.

62. 21 C.F.R. § 202.1(e)(6)(xi) provides that an advertisement may not use "literature, quotations, or references for the purpose of recommending or suggesting conditions of drug use that are not approved or permitted in the drug package labeling." *See also* 21 U.S.C. § 331(d) (prohibiting distribution of a drug for non-approved uses); *id.* § 331(a) (prohibiting distribution

of a misbranded drug); *id.* § 360aaa (permitting dissemination of material on off-label uses only if the manufacturer meets certain stringent requirements).

63. The FDA regulations that fall under the general rubric of 21 C.F.R. § 202.1(e)(6) *et seq*. ban advertisements that are false, lacking in fair balance, or otherwise misleading. Thus, the use of unsubstantiated comparative claims also is prohibited by law. *See* Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 352; 21 C.F.R. § 202.1(e)(6). Specifically, companies such as Abbott may not promote their approved drugs through unsubstantiated comparative claims that exalt their drugs as safer (or more efficacious) than competitor drugs. Such promotion renders a drug "misbranded" and no longer eligible for reimbursement by Federal Programs, including Medicaid and Medicare Part D.

64. The regulations prohibit an advertisement that "contains a representation or suggestion that a drug is safer than it has been demonstrated to be by substantial evidence or substantial clinical experience, by selective presentation of information from published articles or other references that report no side effects or minimal side effects with the drug or otherwise selects information from any source in a way that makes a drug appear to be safer than has been demonstrated." *See* 21 C.F.R. § 202.1(e)(6)(iv).

65. The regulations require drug companies to present a "true statement" of information relating to the side effects, contraindications and effectiveness of the drug use. *See* 21 C.F.R. § 202.1(e)(5) *et seq*. A company violates this regulation if it presents "false or misleading" information about a drug's side effects or does not "fair[ly] balance" information relating to the safety and efficacy of the drug use against information about its side effects and contraindications. *Id.*

66. 21 C.F.R. § 202.1(1)(2) broadly describes "labeling" of a drug as including any material accompanying a drug product that is supplied and disseminated by the manufacturer, packer or distributor of the drug.

67. 21 C.F.R. § 201.56 requires labeling to be "informative and accurate and neither promotional in tone nor false and misleading in any particular," to "contain a summary of the essential scientific information needed for the safe and effective use of the drug," and prohibits "implied claims or suggestions of drug use if there is inadequate evidence of safety or a lack of substantial evidence of effectiveness."

68. The FDA has interpreted oral communications as falling under the umbrella of "labeling."

69. 21 C.F.R. § 99.101 *et seq*. lays out the stringent requirements that must be met by the manufacturer before it may disseminate any materials on unapproved or new uses of marketed drugs. This material must be in the form of an unabridged reprint or copy of a published, peer-reviewed article that is considered "scientifically sound" by experts qualified to evaluate the safety or effectiveness of the drug involved. *See* 21 C.F.R. § 99.101(a)(2). The FDA does not consider abstracts of publications to be "scientifically sound." 21 C.F.R. § 99.101(b). Unabridged reprints or copies of articles shall not be disseminated with any information that is promotional in nature. 21 C.F.R. § 99.101(b)(2).

70. Furthermore, the manufacturer must not disseminate materials that are "false and misleading," such as those that only present favorable information when unfavorable publications exist, exclude mandatory information about the safety and efficacy of the drug use, or present conclusions that "clearly cannot be supported by the results of the study." 21 C.F.R. § 99.101(a)(4).

71. In sum, the off-label regulatory regime protects patients and consumers by ensuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific government body – the FDA. And, the prohibition on unsubstantiated comparative claims protects patients and consumers by ensuring that the prescription and use of approved drugs is not based on misleading marketing tactics.

VI. PROMOTING THE DEPAKOTE® PRODUCTS FOR OFF-LABEL USES

A. THE DEVELOPMENT OF THE DEPAKOTE® PRODUCTS AND APPROVAL BY THE FDA TO TREAT BIPOLAR DISORDER AND EPILEPSY

72. The Depakote® Products are generally included in the group of anti-epileptic drugs ("AEDs"), otherwise known as anticonvulsants. AEDs are a diverse group of pharmaceuticals used in the treatment of patients with epilepsy.

73. Patients with epilepsy have a brain disorder where clusters of nerve cells signal abnormally, thereby making seizures likely. AEDs are designed to suppress the rapid and excessive firing of neurons that start a seizure, thereby reducing the likelihood of seizures.

74. AEDs are also increasingly being used in the treatment of bipolar disorder.

75. Depakote® (divalproex sodium), was first approved for marketing by the FDA on March 10, 1983 for the treatment of epilepsy. Divalproex sodium is a stable co-ordination compound comprised of sodium valproate and valproic acid in a one-to-one molar relationship and is formed during the partial neutralization of valproic acid with 0.5 equivalent of sodium hydroxide. Chemically it is designated as sodium hydrogen bis(2-propylpentanoate). The U.S. composition of matter patent for Depakote® expired in 2008. Depakote® achieved sales of $1.3 billion in 2008, a decrease of 13 percent from 2007. Abbott lost its market exclusivity for Depakote® in July of 2008, and began to face generic competition in the second half of 2008. At all times material hereto, Depakote® was promoted off-label by Defendant Abbott *for the*

treatment of agitation and aggression associated with dementia in the elderly and numerous other conditions, described herein.

76. Depakote Sprinkles® is the capsule form of Depakote®, and was approved by the FDA on September 12, 1989 *for the treatment of epilepsy in children.* At all times material hereto, Depakote Sprinkles® was promoted off-label by Defendant Abbott *for the treatment of agitation and aggression associated with dementia in the elderly and numerous other conditions, described herein.*

77. The Depakote® Products also include Depacon® and Depakene®. Depacon® is the intravenous form of Depakote®, and was approved by the FDA on December 30, 1996 for the treatment of patients with (a) complex partial seizures that occur either in isolation or in association with other types of seizures, (b) for use as sole and adjunctive therapy in the treatment of patients with simple and complex absence seizures, and (c) adjunctively in patients with multiple seizure types that include absence seizures. Depakene® is the liquid form of Depakote® and was first approved by the FDA on February 28, 1978 for the treatment of patients with (a) complex partial seizures that occur either in isolation or in association with other types of seizures, (b) for use as sole and adjunctive therapy in the treatment of patients with simple and complex absence seizures, and (c) adjunctively in patients with multiple seizure types that include absence seizures.

78. Depakote ER® (an extended release divalproex sodium formulation) was first approved by the FDA for marketing on August 4, 2000 only for the treatment of migraines. Depakote ER® was later approved for treatment of epilepsy, and for use in children and adolescents ages 10 to 17 on August 14, 2003, and then later for bipolar disorder on December 6, 2005. At all times material hereto, since it was introduced into the market, Depakote ER® was

promoted off-label by Defendant Abbott *for the treatment of agitation and aggression associated with dementia in the elderly and numerous other conditions, described herein.*

79. The Depakote® Products have been heavily used for the treatment of Medicaid, Medicare Part D, VA, and FEHBP recipients -- particularly for treatment of the elderly. For Medicaid alone, Depakote® and Depakote Sprinkles' reimbursements from 1991 through 2008 total about $5.5 billion. Following its launch in 2000, Medicaid's expenditures for Depakote ER® from 2000 to 2008 were $2.1 billion. The Medicaid payments by year for Depakote® (including Depakote Sprinkles®), Depakote ER® and Depakene® are:

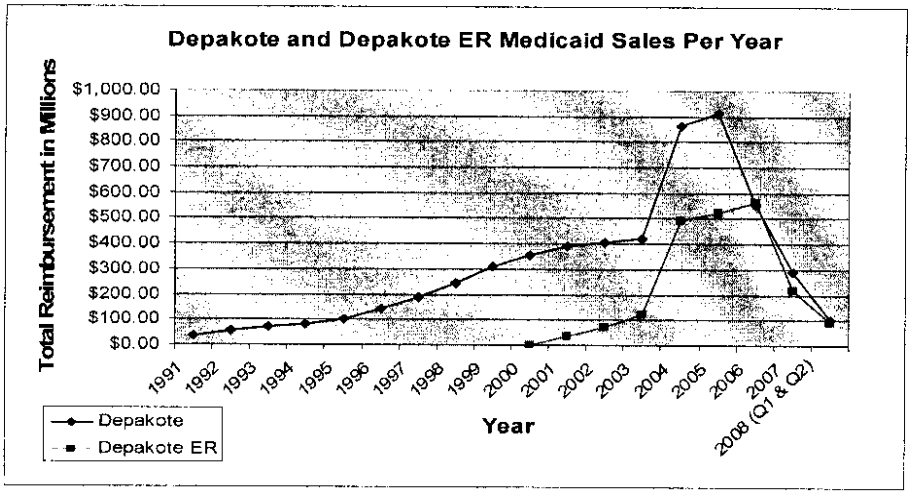
Depakote® Family Medicaid Sales Per Year[1]

Year	Depakote®	Depakote ER®	Depakene®
1991	$35,491,151.93		$5,898,381.70
1992	$54,397,519.13		$7,683,955.38
1993	$70,643,620.20		$8,357,037.12
1994	$81,875,759.83		$7,458,692.00
1995	$103,815,475.92		$6,761,852.88
1996	$144,479,524.30		$6,985,971.62
1997	$185,955,150.63		$6,592,898.64
1998	$243,583,360.56		$6,574,045.15
1999	$309,677,997.99		$6,876,832.99
2000	$357,586,802.15	$1,158,397.91	$7,005,819.49
2001	$393,194,206.86	$35,488,666.39	$6,701,636.83
2002	$405,158,352.20	$72,547,463.56	$5,581,322.53
2003	$421,885,344.69	$121,571,968.76	$4,760,363.37
2004	$865,287,606.17	$490,983,425.65	$14,353,088.74
2005	$911,802,483.52	$521,540,912.69	$16,989,153.44
2006	$553,062,102.59	$562,283,148.64	$3,994,134.66
2007	$286,915,129.92	$219,410,137.18	$3,252,019.59
2008 (Q1 & Q2)	$102,055,458.55	$88,979,980.11	
TOTAL:	$5,526,867,047.14	$2,113,964,100.89	$125,827,206.13
1998 to 2008 Total:	$4,850,208,845.20	$2,113,964,100.89	$76,088,416.79

[1] Depacon® has not been included in these calculations because it is an intravenous drug mainly used in hospital emergency rooms and, therefore, is not included in Medicaid's out-patient drug information.

Total Medicaid payments for the Depakote® Products from 1998 to 2008 were $7,040,261,362.88. An estimated half of these payments were for LTC patients, of which an estimated 85 percent to 90 percent were off-label.

80. The growth of the off-label Medicaid sales of the Depakote® Products from 1998, the date when the Fraudulent Marketing Scheme was initiated, is dramatic:



Although Depakene®'s total Medicaid reimbursements are small in comparison to Depakote® and Depakote ER®, Depakene® saw a 300 percent revenue increase in 2004 on the same pattern as Depakote® and Depakote ER®.

B. PHARMACY BENEFITS IN LONG-TERM CARE FACILITIES

81. Unlike other health care services, long-term care is primarily intended to help with daily activities rather than to treat medical conditions. Overall demand for long-term care is expected to expand considerably over the next 50 years, as the number of U.S. residents over age 85—who are most likely to need long-term care—is projected to rise from 5 million in 2006 to 9 million in 2030 to 19 million by 2050.

82. Vulnerable residents of LTC facilities must rely almost exclusively on dedicated LTC pharmacies offered through the Institutional Pharmacy Defendants in order to obtain their

prescription drugs. The LTC pharmacies, also called "institutional pharmacies," are a type of specialized retail pharmacy. LTC pharmacies address the special needs of nursing homes and other LTC facilities by providing packaging for controlled administration (called "unit-dose supply" or "bubble packs"), and special services that are more extensive than those provided by many retail pharmacies. These special services include: quality assurance checks, emergency drug kits, medication carts, regular and emergency (24-hour-a-day) delivery services, and in-service training programs for nurse aides, nurses, and other professional facility nursing staff.

83. As a result of considerable industry consolidation, two national chains provide the bulk of institutional pharmacy services to nursing homes and other LTC facilities: Omnicare and PharMerica. In 2007, Omnicare and PharMerica collectively accounted for some 95 percent of the total revenue generated in the institutional pharmacy market, totaling approximately $7.3 billion. Omnicare's $6.02 billion in revenue accounted for 80 percent of the total LTC market share, and PharMerica's $1.2 billion accounted for the another 15 percent of the LTC market.

84. Defendants Omnicare and PharMerica have at all material times had contracts with nursing homes and other LTC facilities to provide medications and consultant services for residents/patients. They capture a large volume of customers in this way. Defendants Omnicare and PharMerica have developed "drug formularies" (lists of preferred drugs for dispensing to residents of nursing homes and other LTC facilities), and use them in many states that do not have Medicaid preferred drug lists ("PDLs") applicable in the LTC facility setting.

85. At all times material hereto, Defendants Omnicare and PharMerica (and/or their predecessors in interest) had agreements with Defendant Abbott, which paid Omnicare and PharMerica rebates and other remuneration in exchange for their agreement to convert prescriptions from other competing (and often less-expensive) psychotropic drugs to Defendant

Abbott's Depakote® Products and/or (following the launch of Depakote ER® in 2000) to convert from Depakote® to Depakote ER®.

86. Until the introduction of Medicare Part D in January 2006, Medicaid provided prescription drug coverage for approximately 70 percent of nursing home residents. An additional 15 percent of nursing home residents are admitted following a qualifying stay at an acute care hospital, which means that their care, including prescription drugs, may be covered by Medicare Part A. Under the Part A benefit, nursing homes are paid a global payment that includes the cost of prescribed drugs. The remaining 15 percent of nursing home residents pay for their prescription drugs from their own resources or from third-party insurance. This final group of residents typically spend their resources down to the level at which they will eventually qualify for Medicaid or enrollment in a qualified Medicare prescription drug plan.

87. Most residents of LTC facilities are age 65 or older, and the percentage of each age group residing in nursing homes increases with age. According to the HHS, approximately 1.5 million Americans reside in the nation's 16,400 nursing homes on any given day. In 2006, approximately 2.8 million (7.5 percent) of the 37.3 million persons aged 65 and over in the U.S. had a nursing home stay, while approximately 1.2 million (22.6 percent) of the 5.3 million persons aged 85 and over had a nursing home stay. According to the American Association of Homes and Services for the Aging ("AAHSA"), the elderly use about four times as many prescription products as the rest of the population, and by 2026 the population of Americans over age 65 is expected to increase to 71.5 million. Also, according to the AAHSA, there are more than 1.4 million nursing home residents in the United States.

VII. ABBOTT DELIBERATELY MISLEADS HEALTH CARE PROFESSIONALS CONCERNING THE SAFETY OF THE DEPAKOTE® PRODUCTS

88. The use of the Depakote® Products is associated with a number of serious medical risks. The Product Inserts ("PIs") for the Depakote® Products include Boxed Warnings for hepatotoxicity (resulting in fatalities), teratogenicity (such as neural tube defects), and pancreatitis (life-threatening cases have been reported). The drugs are contraindicated in patients with hepatic disease or significant hepatic dysfunction, in patients with known hypersensitivity to the drug, and in patients with known urea cycle disorders. In addition to these Boxed Warnings, the Warnings and Precautions sections for Depakote® disclose numerous additional risks, including somnolence in the elderly, thrombocytopenia, hyperammonemia and encephalopathy associated with concomitant topiramate use, multi-organ hypersensitivity reactions, and suicidal ideation, as well as cautions regarding drug plasma monitoring, effects on ketone and thyroid function tests, and effects on HIV and CMV virus replication. The PI for Depakote ER® contains a warning related to hypothermia. The Depakote® Products are also associated with a number of common adverse reactions for both their epilepsy and mania indications.

89. From the time the Depakote® Products came on the market in 1983 through December 2007, there have been 14,402 adverse events reported in the United States, of which 9,861 were serious adverse events ["serious adverse events" per the regulatory definition (21 CFR § 314.80)]. During this time, there have been 561 reported deaths from use of the Depakote® Products. It has been estimated that only 1 percent to 10 percent of adverse events are ever reported to the FDA. Nebeker, *et al.*, *Clarifying Adverse Drug Events: A Clinician's Guide To Terminology, Documentation, and Reporting,* 140 ANNALS OF INTERNAL MEDICINE, 1795 –801 (2004).

90. Defendant Abbott regularly engaged in deceptive and misleading promotion of the safety of the Depakote® Products, even downplaying serious known health risks. Sales representatives were instructed to detail the fact that the Depakote® Products were safe to use and had fewer side effects than competing drugs. Abbott engaged in a widespread promotion of the Depakote® Products as safe to treat the elderly suffering from dementia despite having warnings on the label against the risks of such use: "No patients above the age of 65 years were enrolled in double-blind prospective clinical trials of mania associated with bipolar illness. In a case review study of 583 patients, 72 (12 percent) were greater than 65 years of age. A higher percentage of patients above 65 years of age reported accidental injury, infection, pain, somnolence, and tremor. Discontinuation of valproate was occasionally associated with the latter two events. It is not clear whether these events indicate additional risk or whether they result from preexisting medical illness and concomitant medication use among these patients. A study of elderly patients with dementia revealed drug related somnolence and discontinuation for somnolence. . . ."

91. Further, because the overwhelming majority of the use of the Depakote® Products was off-label, the FDA did not test whether there was a relationship between the adverse events and the off-label use of the drugs. Instead of going through the FDA process and subsequently being subject to FDA regulations, Abbott continued to market the off-label use of Depakote® as safe without having legitimate scientific or legal bases for such claims.

A. ABBOTT DIMINISHED THE RISK OF SUICIDE AND OTHER ADVERSE EVENTS

92. One area of particular concern was the risk of suicide associated with taking the Depakote® Products. Abbott engaged in a promotion to downplay the risk of suicide in response to a study published in the JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION in 2003, which

found that the risk of suicide was 2.7 times greater for those taking Depakote® than for those taking lithium. *See* Goodwin, *et al.*, *Suicide Risk in Bipolar Disorder During Treatment With Lithium and Divalproex,* 290 JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION 1467 (2003). In response, rather than acknowledging that using the Depakote® Products carried with it an increased risk of suicide, Abbott's Marketing Director for the Neuroscience Franchise, Kevin McRaith, sent all the LTC Sales Force a memo dated September 18, 2003, instructing them on how they should respond to the suicide risk issue, specifically by criticizing the Goodwin study as a retrospective study and thereby "inherently biased." The message was to minimize any concerns from healthcare professionals.

93. However, in February 2008, the FDA announced that it had found that AEDs, including divalproex, double the risks of suicidal thoughts and behavior, and patients taking them should be watched for sudden behavioral changes. The FDA announced its conclusion after analyzing 199 clinical trials with 43,892 patients, and found 4 suicides and 105 reports of suicidal symptoms among the 27,863 patients who were given the drugs and 35 reports of suicidal symptoms among the 16,029 patients treated with placebos. As a result, the FDA required 11 AEDs, including divalproex, to add a suicide black box warning on their label. *See* Harris, *F.D.A. Finds Increase in Suicide Symptoms for Patients Using Seizure Medications,* NEW YORK TIMES, February 1, 2008. Unlike its earlier denials of any potential suicide risk associated with use of the Depakote® Products, in response to the FDA's warnings, Laureen M. Cassidy (a spokeswoman for Abbott) was quoted as saying: "This is important information for care-givers to monitor patients. . . ."

B. ABBOTT DOWNPLAYED SAFETY RISKS ASSOCIATED WITH ITS OFF-LABEL PROMOTION OF ORAL LOAD DOSING OF THE DEPAKOTE® PRODUCTS

94. A key part of the Fraudulent Marketing Scheme was the deliberate flouting of the PI limits on the dosing of Depakote® through what it referred to as "oral loading," "oral dose-loading," or "rapid stabilization" -- *i.e.*, using much higher starting doses of the Depakote® Products so as to increase its sales revenues. Abbott regularly promoted off-label oral loading of the Depakote® Products in the treatment of bipolar disorder.

95. The Depakote® PI (the identical language appears from at least 2003 in the PI through today) warns that the "frequency of adverse events . . . may be dosed-related. . . . The therapeutic benefit which may accompany the higher doses should therefore be weighed against the possibility of a greater incidence of adverse events." Under "Dosage and Administration" the PI states the "recommended initial dose is 750 mg daily in divided doses." And, it states that, "[d]ue to a decrease in unbound clearance of valproate and possibly a great sensitivity to somnolence in the elderly, the starting dose *should be reduced in these patients."* (emphasis added)

96. Despite the warnings on the PI, Abbott regularly promoted oral loading of Depakote®. For example, beginning in 1999, the Sales Force provided physicians with a reprint of a study by Hirschfeld, *et al., Safety and tolerability of oral loading divalproex sodium in acutely manic bipolar patients*, 60 THE JOURNAL OF CLINICAL PSYCHIATRY 815 (1999), which had concluded that "[a]ccelerated oral loading with divalproex sodium is a feasible and safe method to bring serum valproate concentrations to effective levels rapidly." In their sales meetings, the Sales Force rehearsed the "model call" in which they were to emphasize that Depakote® is the "foundation therapy with flexibility for optimal dosing" and were to urge physicians to increase initial dosing up to 2000 mg. Sales representatives had the Hirschfeld reprint for dissemination until at least 2006.

97. In an April 2002 CME sponsored and funded by Abbott through the Distance Learning Network entitled "Rapid Stabilization Strategies for the Acutely Ill," Dr. Robert Hirschfeld presented a video conference in which he discussed the use of "oral dose loading" in the treatment of the acutely ill, including for acute mania. According to the Study Guide slides, Dr. Hirschfeld made the case for "oral load dosing" of Depakote® of up to double the initial FDA-approved starting dose. The presentation concluded that "Oral loaded Divalproex is safe and well tolerated," "achieves earlier therapeutic serum levels," and "has shown an early efficacy advantage over non-loading." The CME terminated in April 2004.

98. The company regularly retained and paid speakers who promoted off-label oral dose loading of Depakote® in the treatment of bipolar disorder throughout the United States. For example, starting at least as early as January 2003, speakers were provided with an Abbott-approved slide deck entitled "Bipolar Disorder: Oral Loading and the Need for Rapid Stabilization." This slide deck included recommendations from the American Psychiatric Association (which had received funds from Abbott), concluding that oral dose loading of divalproex "is well tolerated and may be more efficacious than a more gradual titration from a lower starting dose." In addition, speakers were to tell attendees that "Divalproex has the ability to be rapidly-loaded to achieve therapeutic blood levels in the treatment of acute mania" and that rapid loading "is safe and effective."

99. In May 2003, Abbott widely disseminated a journal supplement it had sponsored, entitled "Bipolar Disorder & Impulsive Spectrum Letter," from PSYCHIATRIC TIMES, including an article entitled *Dosing Strategies to Ensure Efficacy in Patients with Bipolar Disorder*. This supplement was prepared by Glen Stimmel, a writer for CME, Inc., which discussed the off-label oral loading of Depakote®.

100. Additionally, Abbott's Medical Information Department regularly sent responses to Medical Education Requests, which included off-label information on the oral loading of the Depakote® Products. For example, one letter sent to Dr. Amel Badr, M.D., 260 Terrace Avenue, Hasbrough Heights, New Jersey on October 17, 2005 claimed that "[c]linical trials in the published medical literature suggest that oral loading of divalproex is efficacious and as well tolerated as conventional divalproex dosing."

VIII. ABBOTT'S FRAUDULENT MARKETING OF THE DEPAKOTE® PRODUCTS AIMED AT LTC FACILITIES

101. At all relevant times, Abbott knew that the Depakote® Products were (and are) being paid or reimbursed by Federal Programs, including Medicaid and Medicare Part D, as well as by the *Qui Tam* States.

102. When Abbott decided to employ these illegal marketing practices, it knew, should have known, or it was foreseeable that physicians and pharmacists would routinely and necessarily file claims with Federal Programs for reimbursement for the Depakote® Products even though they were not eligible for such reimbursements.

103. But for Abbott's illegal promotion, these off-label and misbranded prescriptions for the Depakote® Products would not have been written. As a result, Abbott caused the submission of false claims to Federal Programs for reimbursement of the Depakote® Products.

104. Abbott was a beneficiary of these false claims for reimbursement of the Depakote® Products prescriptions largely funneled through the Institutional Pharmacy Defendants.

A. ABBOTT SALES REPRESENTATIVES' OFF-LABEL MARKETING OF THE DEPAKOTE® PRODUCTS WAS DIRECTED AND CONTROLLED BY ABBOTT SENIOR MANAGEMENT

105. At all times material hereto, the doctors to whom Abbott promoted the Depakote® Products reasonably believed that the knowledge that informed their clinical decisions and standards of care derived from the scientific evidence published in medical journals, presented in review articles, and endorsed by thought leaders and trusted organizations at speaker programs and CME events. Abbott's documents show, however, that it engaged in a carefully orchestrated and comprehensive program to exploit physicians' trust in this process of knowledge creation and dissemination. Rather than being the product of unbiased scientific inquiry, the "scientific evidence" supporting off-label use of the Depakote® Products derived from Abbott's carefully designed and orchestrated campaign, in which pre-determined, readily marketable "key messages" formed the basis for the scientific evidence, and not the other way around.

106. Abbott's drug representatives were to (and did) provide seemingly useful services to busy doctors. Along with their tickets to sporting and cultural events, trinkets, doughnuts, and free lunches, Abbott's drug representatives arrived with reprints of articles from medical journals, as well as the drug company's own educational materials summarizing the latest medical research. Most doctors firmly believed that their opinions regarding drugs and scientific evidence were not compromised by these interactions.

107. Since at least 1998, Abbott's sales representatives were to (and did) provide healthcare professionals nationwide with Abbott-approved materials to influence the off-label prescribing of the Depakote® Products, including "approved" clinical studies, industry supplements, and CME materials. These off-label materials were provided to healthcare professionals at one-on-one details, in-services, speaker programs (both CME and non-CME), advisory boards, conferences, dinners, sporting events, and cultural events. Relator Spetter has

provided to the Government thousands of examples of these Abbott-approved materials that sales representatives used to detail the off-label use of the Depakote® Products.

108. The specific intent of Abbott's promotion was to influence physicians to write more prescriptions for the Depakote® Products, including for numerous off-label uses. For example, in 2006 training materials provided to its Depakote® Sales Force entitled "Evidence-Based Selling for Specialty Sales Forces: A Participant Guide," the Company made clear that its plan was to deceptively manipulate the available clinical information physicians would use in making the decision to prescribe the Depakote® Products:

> The Sales Professional enters the picture between diagnosis and treatment which means they also need to understand how physicians use [Evidence Based Medicine] to search for and find applicable studies, critically evaluate the literature and determine clinical significance. Determining statistical significance and clinical relevance is an important trait of the job of the pharmaceutical sales professional. By doing this we help physicians answer the questions: How do they apply the information in the study to their patients? What does this data mean to the physician?

Abbott trained its Depakote® Sales Force to "leverage" clinical information concerning uses (including off-label uses) when planning each sales call. Sales representatives were to pinpoint the study's key findings (including off-label findings), which were then turned into "key selling messages." The training for, and pre-call planning of, the Fraudulent Marketing Scheme was both elaborate and deliberate. Sales representatives were instructed to "spend as much time planning your call as you would on the call itself." This planning gave sales representatives enough time to determine on which points to focus, as well as to prepare for any possible physician objections to the message. Per their Abbott training: "A well-prepared call is more likely to make an impact with the physician." Sales representatives were to demonstrate to physicians that representatives constituted a "knowledgeable resource," were familiar with the

study concepts, and could "speak the physician's language to answer the questions that arise from a study." They were specifically trained to manipulate the message by "[s]often[ing] the language around an unfavorable point and focus[ing] on what the strengths [were]" in order to make their message more compelling. Representatives were trained that they were "selling the validity of your study and the product at the same time."

109. At the conclusion of each sales call, Abbott's sales representatives were to "close" the sale by asking for the physician's agreement to prescribe the Depakote® Products off-label "for what seems reasonable and what can realistically be done by the physician." Upon agreement, they were to "ask the physician first for a change in thinking and then a change in behavior" to prescribe the Depakote® Products off-label. They were instructed that the physician's "thoughts and feelings precede behavior[,] and when the customer 'buys in' you have the opportunity to reinforce 'good decisions' that support the Abbott brand usage."

110. The Depakote® sales representatives regularly role-played sales details in front of sales management at district and national meetings, at which they would hone their off-label message. Representatives were evaluated on their ability to utilize their training in the field. Representatives were supplied with laptop computers to enter "call notes," describing what they did on a particular sales call. Notes from their pre-calling planning and sales calls were included in sales representatives' call notes. These call notes were regularly uploaded to Abbott's mainframe computers and were thereby available for each Abbott district manager, as well as its Sales and Marketing management, who could, and did, track the success of off-label sales calls. In addition, district managers regularly conducted in "ride-alongs" with each of their respective sales representatives, in order to ensure that representatives were promoting the off-label message, as well as to "coach" them on how to improve that message. As such, the off-label

promotion was not only the product of deliberate planning by Defendant Abbott, it was directly supervised and encouraged.

111. Representatives were expected to deliver "core messages" created by Defendant Abbott's Sales and Marketing Department about the Depakote® Products to health care professionals. Sales representatives were expected to weave Abbott's "core messages" into their overall product details. To assist with core message delivery, Defendant Abbott's Marketing Department provided "visual aids" and material that sales representatives could use or distribute during their calls. The messaging and material was created under the supervision of Defendant Abbott's Medical, Regulatory, and Legal Departments to ensure compliance with industry and company policy. Sales representatives were "prohibited" from using aids that had not been approved by Defendant Abbott. Representatives were evaluated on their ability to consistently give a logical, reasonable call-to-action "close" on every sales call to drive product adoption and utilization.

B. ABBOTT CREATES LTC GROUP TO GROW THE OFF LABEL SALES OF DEPAKOTE® AND DEPAKOTE SPRINKLES® FOR AGITATION AND AGGRESSION ASSOCIATED WITH DEMENTIA

112. The Neuroscience Franchise of the Pharmaceutical Products Division of Abbott Laboratories® started the LTC Sales Force in January of 1998 to market the Depakote® Products, at that time primarily Depakote® and Depakote Sprinkles® (Depakote ER® was not approved until 2000).

113. Abbott created the LTC Sales Force to maximize off-label sales for agitation and aggression associated with the treatment of dementia--indications that the company had planned to obtain from the FDA, but which it had decided against due to concerns that the drug caused unacceptable somnolence (*i.e.*, excessive sleepiness) and weight loss. Until this time, Abbott's

sales representatives had sold the Depakote® Products primarily to physicians treating epilepsy and bipolar patients, but realized the huge opportunity available to sell the drugs in the LTC market for the treatment of agitation and aggression associated with dementia and other psychiatric conditions.

114. Relator Spetter joined the initial group of thirty LTC sales representatives in January 1998, also called the "Charter Members" of the LTC Sales Force, who were directed to sell the Depakote® Products for treatment of the elderly. Relator Spetter, along with the other Charter Members, attended highly structured training courses conducted by the company's sales trainers in Abbott Park, Illinois. The company's sales trainers prepared materials outlining the market for sales of Depakote®, including the fact that the majority of LTC patients' pharmacy benefits would be reimbursed by Government programs –Medicaid in particular. *See* Long-Term Care Specialist, Sales Training Manual, p. 7-5.

115. During their training (after they had heard presentations by Abbott's corporate sales trainers instructing them to promote Depakote® only on-label), the Charter Members were taken into a different meeting room where the door was closed and they were given a presentation by Larry Winfield, an experienced Abbott Neuroscience sales representative who had been selling Depakote® for several years. At the meeting, Mr. Winfield instructed the Charter Members that they should ignore Abbott's trainers' instructions to only sell Depakote® on-label, and that instead their primary sales opportunities would be off-label sales in the LTC market for agitation and aggression in the treatment of dementia.

116. In addition, Abbott trained the LTC Sales Force that, among the additional "enhancements [that] are used to win favorable contracts with providers," Abbott would be using the following to increase sales of the Depakote® Products:

- Up-front discounts through a charge-back system to minimize customer outlays and avoid rebate calculations;
- Rebate contracts based on market share performance;
- Bundled product deals in connection with programs implemented to affect market share performance favorably for a particular product or products;
- Extended dating, which allowed pharmacy providers to improve cash flow by deferring payments;
- Price protection (purportedly within the scope of applicable state and federal rules); and
- Availability of specialized packaging intended for the LTC market.

117. In addition, Abbott laid out its scheme to influence LTC decision-makers to use Depakote® through various other kickbacks, unrelated to drug contracting, specifically to "influence pharmaceutical market share in the nursing facility through control over physician prescribing habits and access to nursing facility patients" by providing "value-added" programs, including:

- Regional/local educational symposia for physicians and nurses;
- Nursing in-service programs;
- Market research;
- Clinical research;
- New product information;
- Advisory boards; and

- Support for clinical programs (formulary maintenance, therapeutic interchange programs, disease management programs, and targeted therapeutic recommendations).

See Long-Term Care Specialist, Sales Training Manual, p. 7-5.

118. The LTC Sales Force implemented the Fraudulent Marketing Scheme to increase sales of Depakote® by targeting key decision-makers at the local level for the purposes of maximizing profit from the off-label marketing scheme. This strategy was premised on identifying the key LTC decision-makers responsible for product purchasing and contract compliance, including the directors of pharmacy operations, the purchasing directors, nursing personnel, attending physicians, and the directors of consultant pharmacy services. The directors of consultant pharmacy services were identified as being responsible for "[d]isseminating added-value programs and services to consultant pharmacies." *Id.*

119. Following the training in 1998, the LTC Sales Force began calling on the key decision-makers at institutional pharmacies throughout the United States, including Defendants Omnicare and PharMerica. The LTC Sales Force also began to "detail" geriatric psychiatrists, geriatricians, nursing home medical directors, attending physicians, and directors of nursing.

120. By 2001, the Abbott LTC Sales Force had grown from its original 30 Charter Members to 60 LTC sales representatives, which resulted in significant increases in off-label sales. By 2003, there were over 100 LTC sales representatives. Because off-label marketing is so labor-intensive, the number of Abbott LTC sales reps was increasing at the same time (because of consolidation in the market) the number of institutional pharmacies was actually decreasing.

121. In 2004, to disguise its promotion of the Depakote® Products off-label to LTC facilities through its LTC Sales Force, Abbott merged the LTC group into its hospital group and called the combined group its Special Account Executive Institutional Sales Group or SAE Institutional Sales Group. Even after the change, Abbott continued to promote illegal off-label use of the Depakote® Products in LTC facilities throughout the United States.

122. On December 28, 2005, Abbott's Chairman and CEO, Miles White, sent a congratulatory letter to Relator Spetter announcing that "[b]y staying focused on [patient] needs, you've been able to overcome numerous obstacles and made [the Depakote® Products] our best-selling product ever in the United States."

123. On January 1, 2009, Abbott disbanded the SAE Institutional Sales Group, and thereafter had no specific Sales Force selling in the LTC market.

C. ABBOTT USED CONSENSUS CLINICAL PRACTICE GUIDELINES IT HAD FUNDED TO TOUT OFF-LABEL USE OF THE DEPAKOTE® PRODUCTS FOR TREATMENT OF DEMENTIA

124. From the beginning of the LTC Sales Group in 1998, a key part of Abbott's scheme for off-label promotion of the Depakote® Products was the development and use of clinical practice guidelines. Clinical practice guidelines ("CPGs")—summaries of "expert" opinion which are often used to identify standards of care—are an important source of drug information for physicians. CPGs are typically formulated by panels of experts under the auspices of medical professional societies, non-profit organizations, or quasi-governmental organizations. Many of these organizations, however, are partially or fully financially supported by pharmaceutical manufacturers.

125. CPG panel experts, moreover, often have economic ties to the drug industry via research grants or speaker fees. These financial relationships with pharmaceutical companies

"may create conflicts of interest and a risk of undue influence on judgment both for entities that sponsor the development of clinical practice guidelines and for the individuals who participate in their development." *See* Bernard Lo, *et al.*, CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE, INSTITUTE OF MEDICINE 183 (April 21, 2009), http://books.nap.edu/open book.php? record_id=12598&page=189 (last checked on December 6, 2009).

126. Relationships with the drug industry and conflicts of interest in the development of CPGs exist at both the individual level (*i.e.*, panel participants may have industry ties) and the institutional level (*i.e.*, the sponsoring group may rely on industry funding for guidelines). These relationships raise the possibility of conflicts of interest and undue influence at each step in the guidelines development process. Consensus groups that require industry funding for the development of practice guidelines propose topics that will attract industry funding (*e.g.*, a guideline on how to use a product but not whether it should be used). Among the topics proposed to potential funders, companies may favor topics and questions for which the evidence is most likely to support conclusions favorable to that particular company.

127. The lack of transparency of conflict of interest policies in CPGs "limits the ability of guideline readers to consider financial relationships and conflicts of interest as part of their assessment of the credibility of a set of guidelines." *See* CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE 205.

128. In April 1998, McGraw Hill (in part with financial support from Defendant Abbott) published what purported to be independent CPGs entitled "Treatment of Agitation in Older Persons with Dementia, A Postgraduate Medicine Special Report" (the "Guidelines"), which provided a set of dementia management guidelines for doctors treating the elderly. The

Guidelines were updated in May 2001 and again in January 2005 as part of a CME Series on the treatment of dementia in the elderly. The updates to the Guidelines were also funded by Abbott.

129. The Guidelines were designed to create overwhelming use of certain drug products by producing a set of treatment algorithms (*i.e.*, essentially step-by-step treatment decision trees) approved as first and second line treatments for dementia and its manifestations, which include anger, agitation, and aggression. For example, the Guidelines mandated the use of the most expensive drugs on the market including Depakote®, Depakote Sprinkles®, and (after it was approved by the FDA in 2000) Depakote ER® as first-line treatment for dementia patients, even though this was not a use approved by the FDA.

130. The choice of the Depakote® Products as first line treatment by the Guidelines was not accidental. The initial creation of the Guidelines was underwritten by "unrestricted educational grants" from Abbott (as well as other pharmaceutical companies that marketed the other drugs the Guidelines recommended as first-line therapy). While the Guidelines do not spell out how much Abbott contributed nor Abbott's role in their drafting, they do state that ostensibly "the opinions expressed herein are those of the authors and are not attributable to Abbott Laboratories." The Guidelines also explicitly state that they "may contain recommendations for some medications for uses that are not approved within the United States."

131. Nowhere do the Guidelines disclose any panelists' financial ties to Abbott. Among the "Expert Consensus Panelists," however, were numerous physicians with financial relationships with Abbott. For example, one panelist, Pierre N. Tariot, M.D., University of Rochester School of Medicine, was a frequent Abbott-paid speaker, consultant, and a lead researcher and author on the use of the Depakote® Products in the off-label treatment of agitation and aggression in the elderly, discussed in detail below.

132. Once the Guidelines produced the result that was intended (Depakote® as first line treatment for off-label uses), Abbott provided major funding to disseminate copies of the Guidelines to healthcare care professionals caring for LTC patients throughout the United States. For example, Abbott hired Insight Therapeutics, LLC—a Norfolk, Virginia company—to produce a pocket version of the Guidelines (the "Pocket Guide") to be used as part of CME courses that Abbott sponsored. Insight Therapeutics states that the Pocket Guide was "supported through an unrestricted educational grant from Abbott Laboratories." The Guide does not mention how much Abbott paid to have the Pocket Guide produced, nor does it describe the extent of Abbott's involvement in its creation.

133. The Pocket Guide, among other things, discusses medications that can be used to treat dementia and associated behavioral symptoms, and bases the recommendations on "selected peer-reviewed literature, editorial advisors' opinions," and the Guidelines. The "selected peer-reviewed literature" is not identified in the Pocket Guide, nor is the basis for the editorial advisors' opinions explained anywhere. Instead, the Pocket Guide was a paid-for marketing tool, which Abbott then used extensively to promote the off-label use of the Depakote® Products.

134. In addition, as part of the ReView program discussed in detail below, in 2000, Insight Therapeutics prepared a CD version of the Guidelines, funded by an educational grant from Abbott, for dissemination to Omnicare consultant pharmacists as CME events. The CD is complete with the Pocket Guide, PowerPoint presentations that discuss the off-label use of the Depakote® Products for the treatment of agitation and aggression associated with dementia, presentations for family members on the treatment options for dementia, and draft letters from Omnicare to treating physicians, asking them to change prescriptions to an off-label use of the

Depakote® products. The CD was all promotional and off-label. Abbott controlled the content and made sure the off-label message was clearly articulated.

135. Thousands of copies of the Pocket Guide were given to Abbott's Sales Force to use in promoting the off-label use of the Depakote® Products to LTC healthcare professionals. During in-services and sales details, Abbott LTC sales representatives regularly used the algorithms in the Pocket Guides to promote the Depakote® Products off-label as first-line treatment of the elderly suffering from agitation and aggression associated with dementia.

136. In addition, the Guidelines were converted—again with the financial support from Defendant Abbott and other drug makers (as well as from patient support groups like the Alzheimer's Association and the American Federation for Aging Research)—into a promotional piece entitled "Treatment of Dementia and Agitation: A Guide for Families and Caregivers"(hereinafter the "Family Guide"). The Family Guide specifically promoted the off-label use of Depakote®:

> Divalproex was developed as a treatment for epilepsy and is also used to stabilize mood in bipolar disorder (manic-depressive illness). Divalproex can help people with dementia that [sic] are showing aggression or anger. It is often combined with an anti-psychotic medicine.

The Family Guide at 107, *see* http://www.psychguides.com/Dementia percent20Handout.pdf.

137. Through extensive use of the Guidelines, the Pocket Guide, and the Family Guide, Abbott deliberately engaged in the widespread, illegal off-label promotion of the Depakote® Products for the treatment of agitation and aggression associated with dementia. In so doing, Abbott deliberately bypassed governmental safeguards and scientific review by promoting the algorithms as treatment models developed by a panel of unidentified and/or biased "experts."

138. In furtherance of the Fraudulent Scheme, Defendants Omnicare and PharMerica also used the Pocket Guide as a promotional tool. Abbott provided thousands of copies of the Pocket Guide to consultants working for Defendants Omnicare and PharMerica, who then used the Pocket Guides to promote the Depakote® Products to healthcare care professionals—including physicians treating patients in nursing homes, nursing home medical directors, directors of nursing, and other staff—as first-line treatment for dementia-associated anger, aggression, and agitation.

139. On the cover of the Pocket Guides, Abbott misleadingly printed either the names "Omnicare" or "PharMerica" along with each company's logo to make it appear that these defendants were sponsoring the Pocket Guide. Essentially, in this way (and as further described below) Omnicare and PharMerica consultants became the "Trojan horse" promotional sales force for Defendant Abbott's off-label marketing scheme.

140. The Pocket Guides were a "win/win" for Defendants Abbott, Omnicare, and PharMerica. Abbott made sure healthcare professionals received the off-label message, and both Omnicare and PharMerica assisted in the "pull through" of the Depakote® Products under their lucrative rebate contracts with Abbott (described in more detail below), which resulted in significant profits for Omnicare and PharMerica.

141. As a result of Abbott's off-label marketing scheme, the sales of the Depakote® Products nationwide grew such that by 2000 an estimated 85 to 90 percent of the LTC use of the Depakote® Products was off-label, an estimated 85 percent of which was for Medicaid and Medicare patients.

D. ABBOTT DETAILS THE DEPAKOTE® PRODUCTS OFF-LABEL TO HEALTH CARE PROFESSIONALS

142. It is indisputable that expenditures for drug detailing increase sales. "Detailing" is the one-on-one promotion of drugs to physicians by pharmaceutical sales representatives, usually through regular office visits, free gifts, and friendly advice, when "drug reps go to doctors' offices to describe the benefits of a specific drug." Daniel Carlat, *Dr. Drug Rep.*, NEW YORK TIMES MAGAZINE, Nov. 25, 2007, at 67.

143. Medical detailing is a large field, employing over 90,000 sales representatives, or one detailer for every 4.5 doctors. The vast majority of doctors—eighty-five to ninety percent—speak with drug detailers, and most consider the information the detailers provide helpful and accurate. Drug representatives ostensibly provide useful information for physicians as they address "difficult problems in treating patients." Perala *et al.*, *Lifetime Prevalence of Psychotic and Bipolar I Disorders in a General Population,* 64 ARCHIVES OF GENERAL PSYCHIATRY 1892 (2007).

144. Numerous studies have shown that pharmaceutical company details and gifts influence drug prescribing in the direction of the company's product, even when practitioners believe they are not susceptible to influence. *See* Wazana, *Physicians and the Pharmaceutical Industry: Is A Gift Ever Just A Gift?* 283 JAMA 373–380 (2000). A major concern is that, as a result of industry influence, inaccurate, incomplete, or otherwise biased information based on the results of pharmaceutical-sponsored clinical trials may be incorporated into practice guidelines that ultimately become treatment recommendations, which could lead to established medical policies.

145. The Abbott LTC Sales Force engaged in many off-label detailing activities, including "lunch 'n learns," breakfasts, dinner meetings, preceptorships, grand rounds, mini-

fellowships, and in-service training, for the purposes of spreading Depakote® Products' brand message regarding off-label use and thereby raising sales.

1. Detailing P&T Committees to Influence Formulary Selection of the Depakote® Products

146. Many healthcare organizations, such as hospitals, institutional pharmacies, state Medicaid agencies, and managed care organizations, maintain lists of preferred drugs that can be prescribed by healthcare professionals within that organization or which are eligible for reimbursement by that organization. These lists are commonly called "formularies." The Pharmacy and Therapeutics ("P&T") Committee of an organization decides which pharmaceutical products are included on the formulary. P&T Committees typically make formulary decisions based upon assessments of safety, efficacy, tolerability, and increasingly cost-effectiveness. In some cases, organizations with P&T Committees may be acting on behalf of Medicaid, Medicare Part D, or other Government healthcare programs. Members of P&T Committees are expected to avoid both actual and apparent conflicts of interest when making formulary decisions.

147. Defendant Abbott's Depakote® Sales Force in many instances engaged in promotions to influence P&T Committee members to add the Depakote® Products to their formularies. For example, Abbott sales representatives:

- Singled out P&T Committee members for special attention in order to influence their decisions to add the Depakote® Products to their formularies;
- Provided details and in-services to P&T Committee members touting the off-label uses of the Depakote® Products; and

- Called on P&T Committee members for special promotions while a formulary decision was pending to add Depakote ER®, including unsupported superiority claims concerning Depakote ER®.

148. For example, in July 2004 Abbott Institutional SAE Nick Lake engaged in a detail deliberately to influence Clarian Health of Indianapolis, Indiana (which consists of Methodist Hospital, Indiana University Hospital, and Riley Children's Hospital).

149. At the time, Abbott was about to lose patent protection on Depakote®, so was working to influence health plans to add Depakote ER® to their formularies.

150. Clarian did not have Depakote ER® on its formulary and any Depakote ER® prescription was converted back to Depakote® by the Clarian pharmacy. In order to influence the addition of Depakote ER® to the Clarian formulary, Lake first found out who the P&T Committee members were, and then set up regular in-services with the Clarian pharmacy, as well as the psychiatry department and the neurology department at which he promoted unsupported comparative claims of Depakote® to Depakote ER®. During the in-services, he requested that other Clarian practitioners submit requests for Depakote ER® to be added to the formulary. Lake also focused on one physician in particular who was part of the P&T Committee and was in the Clarian Geriatric practice, and made sure that he obtained that physician's support. Lake successfully got Depakote ER® added to the Clarian formulary.

151. Other such promotional activity aimed at influencing key P&T Committee members to put the Depakote® Products on LTC formularies, in particular institutional pharmacy P&T Committees such as those from Defendant Omnicare, is described in detail below.

2. Abbott's In-Services to Promote the Off-Label Use of the Depakote® Products

152. As part of the Fraudulent Marketing Scheme, the LTC Sales Force conducted in-services for nursing home staff and for consultant pharmacists (including for consultants working for Defendants Omnicare and PharMerica). For example, as he was directed by his manager, Relator Spetter provided an in-service training at the Life Care Center of Vista, California on August 1, 2000, entitled "Managing Behaviors in Long-Term Care," which discussed the off-label use of Depakote® and Depakote Sprinkles®.

153. In addition to presenting on the off-label uses of Depakote®, Defendant Abbott funded a 1998 CME in-service on a CD prepared by Creative Care Consulting, Inc. from Clark, New Jersey. Included in the packet of CME information was a videotape entitled "Treatment of Aggression in Elderly Dementia Patients," which depicted actors pretending to be nursing home residents suffering from dementia. The video then showed a round table discussion of the treatment options for the actor patients involving Pierre Tariot, M.D. (a recipient of considerable Abbott research monies and speaker fees); Thomas J. Cali, Pharm.D.; and Laura J. Jakimovich, R.N., M.S.. The videotape began with a banner from either "Omnicare" or "PharMerica," misleadingly giving the impression that the video was prepared by one of these institutional pharmacies. Inevitably, after considering the various options for the make-believe patients, the health care team chooses Depakote® as the treatment of choice for the elderly patient's aggression associated with dementia. Included on the CD are summary materials for drugs to treat aggression. Depakote® is listed as having "[n]umerous controlled and uncontrolled studies" which demonstrate its "effectiveness in the treatment of primary psychiatric disorders with associated mood problems…." The entire presentation was promotional and off-label.

154. Another in-service was entitled "Identifying and Treating Difficult Behaviors in Patients with Dementia," and was sponsored by Abbott with CME credit and prepared by Post-Graduate Institute for Medicine (located in Englewood, Colorado) and Jobson Education (located at 100 Avenue of the Americas, New York, NY 10013). The in-service included a "discussion of published and/or investigational uses of agents that are not indicated by the FDA," and notes that "Post-Graduate Institute for Medicine (PIM), Jobson Education, and Abbott Laboratories do not recommend the use of any agent outside of the labeled indications." The materials also state that the opinions expressed are those of the faculty and not of the sponsors.

155. The two "faculty" for the "Identifying and Treating" CME were Dr. Paul R. Butzine, M.D. (a geriatric psychiatrist from Sun City West, Arizona) and Dr. Jane Winston, M.D. (Family Medicine and Geriatrics, Sun City West, Arizona). Drs. Butzine and Winston had formed a consulting company, GeroSolutions, LLC., Sun City West, Arizona, which purportedly prepared the video and materials. On the written materials, Dr. Butzine discloses that he is on the speaker's bureau for Abbott, a fact not disclosed in the video. The video and CME materials discuss generally the off-label use of the Depakote® Products for the treatment of agitation and aggression in dementia using actors who perform reenactments of elderly patients suffering from dementia. The materials also advertise the fact that AEDs are the "class of choice" for treating agitation and aggression, and that of the AEDs, only carbamazepine and divalproex (Depakote®) have any clinical studies supporting the treatment of agitation and aggression associated with dementia.

156. At the beginning of the video, an actor portrays a patient suffering from dementia who physically threatens a nurse. After considering other potential non-drug and drug therapies, Drs. Butzine and Winston then discuss the Goldberg, Tariot, and Porsteinsson studies (discussed

below), explaining how the studies support the off-label use, without disclosing that the use was, in fact, off-label. After discussing all the off-label advantages of Depakote®, the video ends with the same actor, this time demonstrating how the actor's agitation and aggression is now under control, presumably from using Depakote® off-label.

157. The Abbott LTC Sales Force used this video promotion (and numerous other videos Relator Spetter has provided to the Government) at regular in-services, beginning with its release in October 2004 and continuing through 2006, throughout the United States as part of the off-label promotion of the Depakote® Products.

158. One such in-service was held by Relator Spetter at Paradise Hills Convalescent Center, San Diego, California on July 24, 2006. The topic of the in-service was the off-label use of Depakote Sprinkles® in the LTC setting. The twelve attendees were all licensed nurses. As part of the presentation, attendees watched an off-label promotional videotape and were given pamphlets promoting the off-label use of Depakote Sprinkles®.

3. Abbott Paid Key Physicians Preceptorship Monies in Order to Induce Their Prescribing of the Depakote® Products

159. At all times material hereto, Defendant Abbott's LTC Sales Force paid key high-decile physicians to perform preceptorships in order to influence their prescribing of the Depakote® Products. ("Decile" rankings were a ranking 1 to 10 of overall prescribing by the physician, with 1 being the least number of prescriptions and 10 being the highest number of prescriptions.) Such preceptorship arrangements are a violation of the Anti-Kickback Act. *See* "OIG Compliance Program Guidance for Pharmaceutical Manufacturers," 68 Fed. Reg. 23731 ("Also of concern are compensation relationships with physicians for services connected directly or indirectly to a manufacturer's marketing and sales activities, such as speaking, certain

research, or preceptor or 'shadowing' services. While these arrangements are potentially beneficial, they also pose a risk of fraud and abuse.")

160. One such preceptorship was with Chris Pak of Propac, a consulting pharmacist in Portland, Oregon, who charged $500 per sales representative for a two-day program of "shadowing" Pak. At least one purpose of the preceptorship was to influence Pak to use the Depakote® Products.

161. In one other instance, Relator Spetter, with the approval and direction of his manager, Roger Aumann, in April 2005 conducted a preceptorship with Dr. Robert Yuhas, who practices Geriatric Medicine and Internal Medicine in Solana Beach, California. The fee was $250. At least one purpose of the preceptorship was to induce Dr. Yuhas to prescribe more of the Depakote® Products.

162. In one other instance, Relator Spetter, with the approval and direction of his manager, Roger Aumann, on June 1, 2001 conducted a Depakote ER® preceptorship with Dr. Alan Berkowitz, Medical Director of the Pomerado Hospital Medical Psychiatric Unit (and medical director of several LTC facilities). Dr. Berkowitz was an Abbott KOL, a frequent speaker for Abbott, and a high-decile prescriber. The fee paid for the preceptorship was $500. At least one purpose of the preceptorship was to induce Dr. Berkowitz to prescribe more of Depakote ER®.

E. ABBOTT USED OBRA-87 LIMITS ON "UNNECESSARY DRUGS" TO PROMOTE THE DEPAKOTE® PRODUCTS OFF-LABEL IN LONG-TERM CARE FACILITIES

163. Defendant Abbott's Fraudulent Marketing Scheme to promote the Depakote® Products off label was intended to and did take advantage of OBRA-87 limits on the use of unnecessary drugs in LTC facilities by demonstrating how, unlike traditional anti-psychotics, the Depakote® Products were not subject to the OBRA-87 limits.

164. All LTC facilities participating in Medicare and Medicaid must receive certification for compliance with federal requirements. This is achieved through routine surveys that use deficiency-based measures of performance, known as "deficiency tags." The deficiency tags are themselves categorized as LTC health deficiencies and life-safety deficiencies.

165. Under OBRA-87, each nursing home must employ an outside consulting pharmacist who is responsible for the quality of pharmaceutical services, including ensuring that all drugs are accurately dispensed and administered in the facility. In particular, the pharmacist must conduct a drug regimen review for each patient at least once a month. 42 CFR § 483.60.

166. Psychotropic medications (also described as "psycho-pharmacologic," "psychoactive," or "psychotherapeutic" medications) are drugs that affect brain activities associated with mental processes and behavior. They are divided into four broad categories: anti-psychotic, anti-depressant, anti-anxiety, and hypnotic. Where these medications are used when less aggressive treatment could be effective, they are considered to be "chemical restraints." 42 CFR § 483.13(a).

167. In addition to prohibiting the use of unnecessary drugs (42 CFR § 483.25(l)), the regulations specifically address the use of anti-psychotic drugs. Under the OBRA-87 provisions, residents who had not previously used anti-psychotic drugs were prohibited from receiving these drugs unless anti-psychotic drug therapy was necessary to treat a specific condition, as diagnosed and documented in the clinical record. Further, residents who used anti-psychotic drugs must receive gradual dose reductions and behavioral interventions, unless clinically contradicted, in an effort to discontinue the drug-use. 42 CFR § 483.25(l),(2).

168. Beginning at least as early as 1999, Abbott developed a plan to promote the Depakote® Products off-label use as superior to psychotropic drugs (including in particular the

anti-psychotic drugs), using OBRA-87 limits as the focal point. For example, Abbott retained Chris Pak, MS, RPh, FASCP, the Clinical Services Manager for Propac Pharmacy (now a part of Omnicare) a long-term pharmacy institutional pharmacy based in Oregon, who engaged in numerous meetings with Defendant Abbott's LTC Sales Force to train LTC sales representatives as to how they could promote the off-label use of the Depakote® products to take advantage of the OBRA-87 limits on reimbursement of "unnecessary drugs." One of these training meetings occurred on April 29, 1999. Relator Spetter was in attendance.

169. Specifically, because OBRA-87 did not designate the Depakote® Products as being "anti-psychotics," Abbott's marketing scheme highlighted (1) the off-label use of the Depakote® Products as replacements for anti-psychotics and anti-anxiety medications, and (2) the flexibility enjoyed by prescribing the Depakote® Products off-label, which did not exist with traditional anti-psychotics that were subject to the OBRA-87 limits:

- First, Abbott promoted that the Depakote® Products could be used to treat psychotic disorders without the documentation required for the traditional antipsychotic drugs.
- Second, Abbott promoted the Depakote® Products (which, unlike the anti-psychotic drugs, under OBRA-87 had strict dosing limits and required dose reduction twice a year) as having greater dosing flexibility and no requirement to reduce dosing twice a year.
- Third, Abbott detailed that LTC facilities could avoid CMS scrutiny under the "unnecessary drug rule" by prescribing the Depakote® Products, which provided an alternative to other traditional anti-anxiety drugs that were subject to the OBRA-87 limits.

- Fourth, Abbott promoted that the obligations of nursing staff to implement and maintain paper work was significantly reduced for the Depakote® Products because the routine quantification of behaviors and maintenance of flow records that were required for anti-psychotic drugs under OBRA-87 did not apply to the Depakote® Products.

170. Another such training presentation was given on July 1, 1999 by Tom Snader, Pharm.D., a Depakote® KOL from Sellersville, Pennsylvania, and head of TCS Pharmacy Consultants. During the presentation, Snader provided training concerning how Abbott could take advantage of the OBRA-87 unnecessary drug rules in its promotion of the Depakote® Products.

F. USING MISLEADING CLINICAL STUDIES FUNDED BY ABBOTT IN THE MARKETING OF THE DEPAKOTE® PRODUCTS

171. Clinical trials provide the empirical data upon which the FDA determines a drug's safety and efficacy and doctors make professional judgments about the relative risks and benefits of a drug and whether it is appropriate to prescribe for their patients.

172. Oftentimes, clinical studies sponsored by drug companies are used as marketing tools rather than as valid scientific data upon which health care professionals can rely. According to Harold Sox, M.D., editor of Annals of Internal Medicine, and Drummond Rennie, M.D., deputy editor of JAMA, the following are indicia of marketing masquerading as science: an open-label design, no control group, a very large projected enrollment relative to the importance of the question, a short-term study of a chronic disease, or a study of an already approved drug. Sox, *Seeding Trial: Just Say "No,"* 149 ANNALS OF INTERNAL MEDICINE 279-280 (2008), available at http://www.annals.org/content/149/4/279.full?etoc.